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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,596	01/21/2004	Wilfred Wayne Lauth	14217.1USC1	4255
23552	7590	05/17/2007		
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER RAE, CHARLESWORTH E	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 05/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/761,596

Applicant(s)

LAUTT, WILFRED WAYNE

Examiner

Charlesworth Rae

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 17-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/26/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. By Amendment filed February 5, 2007, new claims 18-29 have entered.

Applicant's arguments, filed 2/5/07, have been fully considered but they are not deemed to be persuasive for reasons previously made of record and reiterated herein. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Applicant's statement that support for the amendment can be found throughout the specification, including page 6, lines 10-15; page 10, lines 13-22, and page 13, lines 10-26, and that no new matter has been added, is acknowledged and made of record. It is noted that applicant's statement that no new matter has been added is not deemed to be persuasive for reasons stated herein.

Applicant's Interview Summary is acknowledged and made of record.

Status of the Claims

Claims 11-13, 17, and 18-29 are currently pending in this application and are the subject of the Office action.

Response to arguments

Applicant asserts essentially the same arguments in the response of February 7, 2007, as previously set forth in applicant's response to the office action dated May 15,

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2005 (see pages 2 to 5 of applicant's Response of 3/8/06; and pages 5 to 7 of applicant's Response of 2/7/07).

Applicant contends that the rejection under 103(a) should be withdrawn because 1) a necessary functional relationship exist between the pharmaceutical composition and the instructions of the kit as claimed, 2) a prima facie case of obviousness cannot be made in the absence of a showing of a suggestion or motivation in the prior art to combine the teachings of the cited prior art references that have previously made of record, and/or a teaching of all the claimed limitations in the prior art. Applicant also opined that 1)

Upon review of the cited case law, Applicant respectfully asserts that the Examiner is applying too high of a standard for functionality. *In Re Miller*, cited by the Examiner, clearly states that there is no requirement for a structural relationship between printed matter and other elements of a combination. The Patent Appeal Board in that case held that what is significant between elements of a claimed combination is not "the structural relationship but functional relationship".

2)

The Examiner newly cites *In re Venezia* as standing for the proposition that kits are drawn to structural attributes of interrelated components parts, and not to activities that may or may not occur. With respect, the applicant respectfully disagrees. *In re Venezia* merely discusses "kits of interrelated parts", and does not stand for the proposition that kits must relate to structural attributes of interrelated component parts in order to patentable, as suggest by the Examiner.

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3)

The Examiner newly cites *In Re Haller* as standing for the proposition that the application of printed matter to old an article cannot render the article patentable. *In re Haller* concerns the labeling of an insecticide. *In re Haller* is distinguished from the present case in that, in the case of pharmaceutical administration, the instructions that specify how to administer the pharmaceutical, under what conditions, and for what ailments, is inherently functionally related to the product, since both the physician and patient require and rely on the instructions in administering a drug.

and 4)

The Examiner again cites *In re Ngai* and *In re Gulack*. As previously pointed out in *Ngai* and *Gulack*, both the prior art and claimed invention contained instructional materials instructing on the claimed use. In contrast, none of the references cited by the Examiner disclose formulating the compositions in a kit with instructional material. None of the cited references, alone or in combination, teach or suggest formulating the compositions into a kit with instructions for administering the compositions to treat insulin resistance. None of the references, alone or in combination, provide a motivation for formulating the claimed structurally modified compositions into a kit with instructions for administering the compositions to ameliorate symptoms of insulin resistance. Reconsideration and allowance is respectfully requested.

Applicant's arguments are not deemed to be persuasive for the reasons previously made of record. That a kit comprising well known compositions comprising nitric oxide donors or agonists, and instructions, which do not further limit the functional characteristics of the composition, is not deemed to be patentable subject matter. In the instant case, the instructions do not limit the contemplated effects to be achieved in practicing the compositional embodiment of the kit. The compositional embodiment would reasonably exhibit the same functional characteristics in the presence or absence of the instructions. To the extent that the instructions do not further limit the functional

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characteristics of the kit, the instructions are given the same effect as the salt form of a compound, which is also not given patentable weight unless the salt form limits the functional characteristics of the compound.

With respect to applicant's arguments of the cited case law of record, applicant's statement that the Examiner is applying too high a standard for functionality is an admission that *In Re Miller* applies to the facts of the instant case. Applicant's proffered argument that *In re Venezia* is not applicable to the facts in the instant case is not deemed persuasive as the facts in *In re Venezia* and the instant case involves the same product i.e. a kit. Applicant's argument that the instructions as claimed in the instant kit is inherently functionally related to the product as claimed, since both the physician and patient require and rely on the instructions in administering a drug, and is therefore distinguishable from the facts *In re Haller* is not deemed to be persuasive as the instructions in the instant application do not further limit the functional characteristics of the "composition" embodiment. Applicant's argument that the prior art references cited in the instant application do not teach the "instructions" embodiment and is therefore distinguishable from the facts of *In re Ngai* and *In re Gulack*, where both the prior art and claimed invention taught the "instructions" embodiment, is also not found to be persuasive because both the instant claimed invention and the facts of *In re Ngai* and *In re Gulack* involve a kit.

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-21 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 21, 26, and 29 recite the ambiguous term “meal.” This term is indefinite because the term “meal” could be reasonably have different meanings. The Compact Oxford English Dictionary defines the term “meal” as 1) any of the regular daily occasions when food is eaten, and 2) the food eaten on such an occasion. In the absence of a precise or concise definition of the term “meal” in the instant disclosure, someone of skill in the art would not reasonably know what the term “meal” means.

Claim rejections – 112 – First Paragraph-

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 22-25 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention.

Specifically, these claims encompass the subject matter "*composition prepared for sale as a pharmaceutical composition*," which was not described in the originally filed application. This is a **new** matter rejection.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-13, 17-29 are rejected under 103(a) for being unpatentable over Adams et al., 6,165,975 and Papandreou et al., 6,171,232 and Salzman et al., 5,958,427 and Klokke-Bethke et al., 5,370,862 and Veronesi et al., 5,580,576.

The discussion of the prior art references made of record in the previous Office action mailed 09/09/05 are incorporated by reference.

The term "meal" as recited, for example, in claims 18, 21, 26, and 29, is reasonably construed as constituting anything that is edible. Based on the **Compact Oxford English Dictionary** definition of the term "*meal*" as including 1) any of the regular daily occasions when food is eaten, this limitation given its broadest reasonable possible interpretation is construed to mean any meal. Adams et al. teach food and water were provided ad libitum throughout a study wherein sodium nitroprusside (SNP) was administered to rats (column 17, lines 37-59), which reasonably meets the limitation of "meal."

The term "*composition prepared for sale as a pharmaceutical composition*" is reasonably construed to be subject matter that is within the ordinary knowledge of someone of skill in the art e.g. a pharmacist or a physician.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant invention by modifying the pharmaceutical composition with a reasonable expectation of success in view of the teachings of Adams et al., 6,165,975 and Papandreou et al., 6,171,232 and Salzman et al., 5,958,427 and Klokke-Bethke et al., 5,370,862 and Veronesi et al., 5,580,576.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

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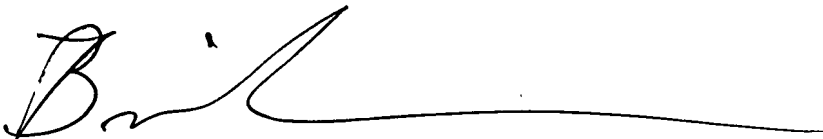
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

13 May 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'B. Kwon', followed by a long horizontal line extending to the right.